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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,681	01/21/2004	William J. Wechter	3829.04	5273

7590 12/06/2006

HANA VERNY
PETERS, VERNY, JONES & SCHMITT, L.L.P.
SUITE 230
425 SHERMAN AVENUE
PALO ALTO, CA 94306

EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,681	WECHTER ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *11 and 13-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03 May 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-10 and 12 are pending and the subject of this Office Action.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-10 and 12, in the response filed on 06 June 2006, is acknowledged. Since Applicant has failed to disclose alleged errors in the restriction requirement, albeit his response is with traverse, Applicant's response to the restriction requirement is deemed unpersuasive.

In short, Applicant's argument is not found persuasive because Applicant has failed to negate the reasoning behind the Examiner's requirement of a restriction. Moreover as noted in the Examiner's Office Action requiring restriction, each grouping contemplates a separate and distinct invention. As the examination of multiple inventions that would require an unduly burdensome search on the part of the examiner, restriction is proper.

The restriction requirement is still deemed proper and is now made FINAL.

Objections

Claim 10 is objected to because of the following informalities: Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. More specifically, claim 10 reads "A method according to Claim 10 wherein A comprises

a moiety of ..." Claim 10 cannot depend from itself, but rather, if dependent at all, should depend from a previous claim.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-10 and 12 are drawn to a method, generally, of treating a disease or illness that is inclusive of diabetes, obesity, inflammation, cystic fibrosis, dementia, or neoplastic disease by administering a pharmaceutical composition that comprises a fatty acid inclusive of "a physiologically acceptable ester or salt thereof or a metabolic precursor." The specification is written broadly, simply advising over examples of compounds that may be considered as physiologically acceptable esters, salts thereof and metabolic precursors, that the same will not have a "deleterious effect[] on the consumer" (Specification, p. 13, lines 18-30 and p. 14, lines 1-

11) and further, that phytol is a metabolic precursor to phytanic acid and thereafter, to pristanic acid as a result of metabolic oxidation and some other processes (Specification, p. 14, lines 6-11). These disclosures are insufficient to meet the written description provision of 35 U.S.C. 112, first paragraph.

In short, the specification is lacking sufficient written description to support the genus disclosed in claims 1-10 and 12 of a compound (fatty acid) that includes a physiologically acceptable metabolic precursor or ester thereof, because the acceptable metabolic precursors and esters thereof are not defined clearly. As a matter of law, an adequate written description requires more than a mere statement that the matter claimed is part of the invention accompanied by reference to potential compounds. Disclosure of the compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Claims 1-10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are enabled for oral, topical, and suppository administration of a chemical composition (Specification, page 47 and page 48, lines 1-14) that contains a compound with the generic formula of A-CH(D)-CO_2H as the active ingredient. However, the claimed chemopreventative, therapeutic, prophylactic, or chemoprotective effects on diabetes, obesity, inflammation, cystic fibrosis, dementia, or neoplastic disease linked to the administration of the chemical composition, containing the active ingredient, *supra*, are not supported by the

specification. As a result, the effect of performing the invention by one skilled in the art would be that of undue experimentation.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in organic chemistry is high, the results of experiments to discover treatments for the illnesses and conditions recited in claim 2, is unpredictable. While all of the Wands factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Although the applicant has provided a number of working examples for producing chemical compositions for topical, oral or suppository administration, the applicant has failed to enable a method of treating **any** disease or illness named in the claimed invention through the examples provided.

Admittedly, the Applicant does list a flora of examples of "[d]isease states, by way of illustration and not limitation, that are alleviated by treatment with a compound" (Specification, page 36, lines 14-29). However, the invention does not specifically enable treatment of any of these diseases or illnesses to which claim 2 of the present invention is drawn. The specification

attempts to broaden claim 2 by making the methods claimed applicable to any condition or illness listed therein while failing to enable the treatment of any disease or illness claimed. As such, the art of the claimed invention lacks predictability because the claims are drawn too broadly.

Claim Rejections – 35 U.S.C. §102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by Whyte (U.S. Patent No. 3,579,548).

Claims 1-10 and 12 are drawn to a method of treating an illness or disease that is diabetes, obesity, inflammation, cystic fibrosis, dementia, or neoplastic disease, comprising administering a chemical formulation containing a fat wherein what would normally be the triglyceride fat of the composition is substituted with a fatty acid compound or a metabolic precursor or physiologically acceptable ester thereof. The compound structure is as follows:

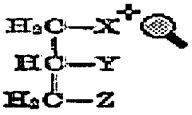
A- CH(D) - CO_2H

where A is an alkyl of 3 to 30 carbons. D is methyl, and when it is bonded to carbon and hydrogen, it forms a metabolic blocker.

Whyte discloses triglyceride esters of α-branched carboxylic acids, and these acids can be used as partial or total replacements for triglyceride fats commonly contained in fatty

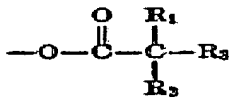
compounds, thereby serving as functional fluids that minimize fat absorption. The general compound as disclosed by Whyte can be defined as follows:

More specifically, the invention provides a novel class of compounds having primary utility as edible low caloric fats, which comprise glycerol ester of α-branched carboxylic acid having the general Formula I



I

wherein X is an α-branched carboxylic acid residue having the Formula II



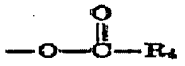
II

wherein

R_1 and R_2 are each selected from alkyl groups of from 1 to 30 carbon atoms, and

R_3 is selected from hydrogen, and alkyl groups of from 1 to 30 carbon atoms, the total carbon atoms in $R_1+R_2+R_3$ being from 8 to 30; and

Y and Z are each selected from X, —OH, and



wherein R_4 is selected from alkyl, and alkene groups of 8 to 30 carbon atoms.

When R1 is an alkyl of 18 carbons, R2 is a methyl and R3 is hydrogen, the resulting compound disclosed by Whyte is a physiologically acceptable ester of a compound identical to the compound in the present application under examination.

Most certainly, a method of treating disease or illness, such as obesity by reducing absorption of fat content by substituting a triglyceride fat with a compound that is a glycerol ester or a physiologically acceptable ester or metabolic precursor thereof is anticipated.

Claim 2 recites the limitation that the diseases presented by generic claim 1 of the instant invention is either diabetes, obesity, inflammation cystic fibrosis, dementia, or neoplastic

disease. Whyte teaches a method of treating obesity by reducing caloric intake (Col. 1, lines 19-35).

Claim 3 recites the limitation that the mammal presented by claim 21 is a human. Whyte teaches reduction of the caloric value of edible fat by decreasing the amount of triglyceride absorbed in the human system (Col. 1, lines 36-43).

Claim 4 recites the limitation that the chemical composition can be administered orally, transdermally, intravenously or by suppository. Whyte teaches edible compounds and food compositions (Col. 1, lines 19-20).

"[T]he discovery of a previously unappreciated property of a prior art composition or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F. 3d 1342, 1347 (Fed. Cir. 1999). Therefore, the claiming of a new use, a new function, or an unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. Rather, it is incumbent upon the Applicants to "prove that subject matter shown to be in the prior art does not possess characteristics relied on," In re Fitzgerald, 205 USPQ 594, by the presently claimed invention.

In consideration thereof, claims 1-10 and 12 of the present application are rejected as being anticipated by Whyte.

Obviousness Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5 6, 9, 11 and 18 of co-pending U.S. Patent Application No. 10/763,111 (Wechter, et al). Albeit the conflicting claims, as written, are not identical, they are not patentably distinct as they contain overlapping subject matter

germane to the heart of the claimed inventions that can be identical when reduced to practice. Essentially, the subject matter of the co-pending applications is the same, just organized differently.

Claim 1 of the instant invention is drawn to a method of treating a disease or illness by the administration of compound A- CH(D) - CO_2H, where A is defined as alkyl of about 3 to about 30 carbon atoms, a substituted alkyl of the same, or an alkene of the same, etc., and D is alkyl of about 1 to 10 carbon atoms or a physiologically acceptable ester or salt thereof or a metabolic precursor thereof. Claim 10 of the same invention depends from claim 1, imposing the further limitation that A comprises the following:

$$E\text{-}CH_2CH_2CH(Y)(CH_2CH_2CH_2CH_2CH(Y))_mCH_2CH_2CH_2\text{-}$$

wherein E is an aliphatic moiety that is alkyl of 1 to about 20 carbon atoms, etc.

Claim 5 of Wechter et al. reads identical to claim 1 of the instant invention in terms of the limitations on the definition of A in the chemical compounds, as found in claim 10 of the instant invention. Where the recitation of the compound of claim 1 in the instant invention is A- CH(D) - CO_2H, the recitation of the compound in claim 5 of Wechter et al. reads A- (metabolic blocker) - CO_2H. The metabolic blocker of claim 5 in Wechter et al. is further limited by claim 6, when defined as having the formula –C(X)(D)- where D is hydrogen and X is defined as an alkyl of 1 to 10 carbon atoms, etc.

Similar to claim 10 of the instant invention, claim 9 of Wechter et al. imposes a further limitation that A in that invention comprises the following:

$$\text{-}(CH_2(CH_2)_aCH(Y)(CH_2(CH_2)_bCH(Y))_m(CH_2(CH_2)_cCH\ (V)\text{-}$$

wherein V and Y are independently alkyl, having from 1 to about 10 carbon atoms.

Claim 11 of Wechter et al., which depends from claim 5 of the same, reads near identical to claim 8 of the instant invention, which depends from claim 1, when defining A of the generic formula in each application. The minor differences overlay, bringing one invention within the purview of the other.

Finally, claim 18 of Wechter et al, which depends from claim 1 of the same, reads near identical to claim 12 of the instant invention, which depends from claim 1 of the same, when assigning a method to which the compound in the generic claim for both inventions is either R,R,R-phytanic acid or R,R,R-pristanic acid or physiologically acceptable salts thereof or R,R,R-phytol. The minor differences overlay, bringing one invention within the purview of the other.

In consideration of the foregoing, the present application's claims are an obvious variation of the chemical compound disclosed in Wechter et al. This is a provisional obviousness-type double patenting rejection, because the conflicting claims have not, in fact, been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H Marschel 11/30/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER